

Serial No. 09/782,320  
AMENDMENT UNDER 37 C.F.R. 1.111  
Attorney Docket No. BVL-102A

**Amendments to the Claims** begin on page 3 of this paper.

**Remarks** begin on page 15 of this paper.

Reconsideration and allowance of the application in view of the following remarks are respectfully requested.

**Amendment to the Claims**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims**

1-24. (Canceled)

25. (Presently Amended) An encapsulated product comprising discrete, solid particles having a substantially uniform shape and a diameter of up to about 10 mm, wherein each particle comprises:

an encapsulant dispersed throughout a plasticized mass comprising starch which is not substantially dextrinized, and at least one component for controlling the rate of release of the encapsulant,

wherein said encapsulant is at least one pharmaceutical component, nutraceutical component, nutritional component, fragrance component, or biologically active component,

wherein said plasticized mass comprises at least about 40% or more by weight of at least one matrix material, based on the weight of the final product, and at least one plasticizer comprising water,

wherein the encapsulant and plasticized matrix material form an at least substantially homogeneous mixture, and

wherein the amount of said encapsulant is from about 1% by weight to about 85% by weight, based upon the weight of the matrix material.

26. (Previously Presented) An encapsulated product according to claim 25 wherein said plasticized matrix material comprises an at least partially gelatinized starch, which starch is not substantially dextrinized.

27. (Presently Amended) An encapsulated product comprising discrete, solid particles having a substantially uniform shape and a diameter of up to about 10 mm, wherein each particle comprises:

an encapsulant dispersed throughout a plasticized mass comprising starch which is not substantially dextrinized, and at least one component for controlling the rate of release of the encapsulant,

wherein said encapsulant is at least one pharmaceutical component, nutraceutical component, nutritional component, fragrance component, or biologically active component,

wherein said plasticized mass comprises at least about 40% or more by weight of at least one matrix material, based on the weight of the final product, and at least one plasticizer,

wherein the encapsulant and plasticized matrix material form an at least substantially homogeneous mixture,

wherein the amount of said encapsulant is from about 1% by weight to about 85% by weight, based upon the weight of the matrix material, and

wherein said encapsulant is coated with a film-forming material prior to dispersion within said plasticized mass.

28. (Original) An encapsulated product according to claim 25 wherein said particles are in the form of a tablet, or a pellet.

29. (Original) An encapsulated product according to claim 28 wherein said particles are coated with a film-forming material.

30. (Original) An encapsulated product according to claim 25 wherein said at least one release-rate controlling component is a hydrophobic component.

31. (Original) An encapsulated product according to claim 30 wherein said hydrophobic component is at least one member selected from the group consisting of fats, oils, waxes, fatty acids, emulsifiers, polyolefins, paraffin, polyvinyl acetate and derivatives thereof, and modified starches.

32-33. (Canceled)

34. (Original) An encapsulated product according to claim 25 which has a specific density of from about 800 g/liter to about 1500 g/liter.

35. (Previously presented) An encapsulated product according to claim 25 wherein the length-to-diameter ratio of said particles is from about 0.1 to about 10.

36. (Canceled)

37. (Original) An encapsulated product according to claim 25 wherein said particles have a substantially non-expanded, substantially non-cellular structure.

38. (Original) An encapsulated product according to claim 25 wherein said encapsulant is released in an aqueous or gastric juice environment in an amount of no more than from about 10% in about 1 hour to no less than about 90% in about 24 hours.

39. (Previously presented) An encapsulated product according to claim 25 wherein:  
the amount of the matrix material is from about 60% by weight to about 95% by weight, based upon the weight of the final product, and  
the amount of said at least one component used to control the rate of release of the encapsulant is from about 5% by weight to about 50% by weight, based upon the weight of the matrix material.

40. (Original) An encapsulated product according to claim 39 wherein said particles have a diameter of from about 0.5 mm to about 5 mm and a length-to-diameter ratio of about 0.5 to about 2.

41. (Canceled)

42. (Original) An encapsulated product according to claim 25 wherein said plasticized matrix comprises durum wheat or semolina.

43-45. (Canceled)

46. (Previously presented) An encapsulated product according to claim 25 wherein said encapsulant is at least one member selected from the group consisting of antioxidants, phytochemicals, hormones, microorganisms, prebiotics, probiotics, enzymes, formulations containing zidovudine, macromolecular polypeptides, aromatic nitro and nitroso compounds and their metabolites useful as anti-viral and anti-tumor agents, HIV protease inhibitors, antibiotics, viruses, steroids, oligopeptides, dipeptides, amino acids, fragrance components, adenosine derivatives, sulfated tannins, monoclonal antibodies, and metal complexes of water-soluble texathyrin.

47-49. (Canceled)

50. (Previously Presented) An encapsulated product according to claim 25 wherein said plasticized matrix material is further comprises at least one member selected from the group consisting of cyclodextrins, dextrins, monosaccharides, disaccharides, polyvinylpyrrolidone, copolymers of N-vinylpyrrolidone and vinyl acetate, polyvinyl alcohol, cellulose esters, cellulose ethers, and polyethylene glycol.

51. (Canceled)

52. (Currently Amended) An encapsulated product comprising:  
discrete, solid particles having a substantially uniform shape wherein each particle  
comprises:

a plasticized matrix material in an amount of ~~at least~~ about 40% or more by weight,  
based on the weight of the final encapsulated product, wherein said plasticized matrix  
material comprises starch which is not substantially dextrinized,

an encapsulant dispersed throughout the plasticized matrix material, and  
at least one component for controlling the rate of release of the encapsulant,  
wherein said encapsulant comprises at least one pharmaceutical component,  
neutraceutical component, nutritional component, fragrance component, or biologically  
active component,

wherein said matrix material comprises at least one member selected from the group  
consisting of durum wheat, semolina, wheat flour, wheat gluten, soy protein, hydrocolloids,  
casein, and gelatin, and at least one plasticizer comprising water,

wherein the encapsulant and plasticized matrix material form an at least substantially  
homogeneous mixture, and

wherein the amount of said encapsulant is from about 1% by weight to about 85% by  
weight, based upon the weight of the matrix material.

53. (Original) An encapsulated product according to claim 52 wherein said  
plasticized matrix material comprises an at least partially gelatinized starch, which starch is  
not substantially dextrinized.

54. (Currently Amended) An encapsulated product comprising:

discrete, solid particles having a substantially uniform shape wherein each particle comprises:

a plasticized matrix material in an amount of at least about 40% or more by weight, based on the weight of the final encapsulated product, wherein said plasticized matrix material comprises starch which is not substantially dextrinized,

an encapsulant dispersed throughout the plasticized matrix material, and  
at least one component for controlling the rate of release of the encapsulant,  
wherein said encapsulant comprises at least one pharmaceutical component, nutraceutical component, nutritional component, fragrance component, or biologically active component,

wherein said matrix material comprises at least one member selected from the group consisting of durum wheat, semolina, wheat flour, wheat gluten, soy protein, hydrocolloids, casein, and gelatin, and at least one plasticizer,

wherein the encapsulant and plasticized matrix material form an at least substantially homogeneous mixture,

wherein the amount of said encapsulant is from about 1% by weight to about 85% by weight, based upon the weight of the matrix material, and

wherein said encapsulant is coated with a film-forming material prior to dispersion within said plasticized mass.

55. (Original) An encapsulated product according to claim 52 wherein said particles are in the form of a tablet, or a pellet.

56. (Original) An encapsulated product according to claim 52 wherein said particles are spherical.

57. (Original) An encapsulated product according to claim 55 wherein said particles are coated with a film-forming material.

58. (Original) An encapsulated product according to claim 52 wherein said at least one release-rate controlling component is a hydrophobic component.

59. (Original) An encapsulated product according to claim 58 wherein said hydrophobic component is at least one member selected from the group consisting of fats, oils, waxes, fatty acids, emulsifiers, polyolefins, paraffin, polyvinyl acetate and derivatives thereof, and modified starches.

60. (Canceled)

61. (Original) An encapsulated product according to claim 52 which has a specific density of from about 800 g/liter to about 1500 g/liter.

62. (Previously presented) An encapsulated product according to claim 52 wherein the length-to-diameter of said particles is from about 0.1 to about 10.

63. (Canceled)

64. (Original) An encapsulated product according to claim 52 wherein said particles have a substantially non-expanded, substantially non-cellular structure.

65. (Original) An encapsulated product according to claim 52 wherein said encapsulant is released in an aqueous or gastric juice environment in an amount of no more than from about 10% in about 1 hour to no less than about 90% in about 24 hours.



66. (Original) An encapsulated product according to claim 52 wherein the amount of said at least one component for controlling the rate of release of the encapsulant is up to about 70% by weight, based on the weight of the matrix material.

67. (Original) An encapsulated product according to claim 52 wherein said particles have a diameter of from about 0.5 mm to about 5 mm and a length-to-diameter ratio of about 0.5 to about 2.

68. (Canceled)

69. (Original) An encapsulated product according to claim 52 wherein said matrix material comprises at least one member selected from the group consisting of durum wheat, semolina, wheat flour, wheat gluten, and soy protein.

70. (Original) An encapsulated product according to claim 52 wherein said matrix material comprises at least one member selected from the group consisting of durum wheat and semolina.

71-72. (Canceled)

73. (Original) An encapsulated product according to claim 52 wherein said discrete, solid particles have a diameter of up to about 10 mm.

74. (Canceled)

75. (Previously presented) An encapsulated product according to claim 52 wherein said encapsulant is at least one member selected from the group consisting of antioxidants, phytochemicals, hormones, microorganisms, prebiotics, probiotics, enzymes, formulations

containing zidovudine, macromolecular polypeptides, aromatic nitro and nitroso compounds and their metabolites useful as anti-viral and anti-tumor agents, HIV protease inhibitors, antibiotics, viruses, steroids, oligopeptides, dipeptides, amino acids, fragrance components, adenosine derivatives, sulfated tannins, monoclonal antibodies, and metal complexes of water-soluble texathyrin.

76-78. (Canceled)

79. (Previously Presented) An encapsulated product according to claim 52 wherein said plasticized matrix material further comprises at least one member selected from the group consisting of cyclodextrins, dextrins, monosaccharides, disaccharides, polyvinylpyrrolidone, copolymers of N-vinylpyrrolidone and vinyl acetate, polyvinyl alcohol, cellulose esters, cellulose ethers, and polyethylene glycol.

80. (Canceled)

81. (Previously presented) An encapsulated product according to claim 52 wherein: the amount of the matrix material is from about 60% by weight to about 95% by weight, based upon the weight of the final product, and the amount of said at least one component used to control the rate of release of the encapsulant is from about 5% by weight to about 50% by weight, based upon the weight of the matrix material.

82. (Original) An encapsulated product according to claim 52 wherein said encapsulant comprises at least one member selected from the group consisting of enzymes and microorganisms.

83. (Currently Amended) An encapsulated product comprising discrete, solid particles having a substantially uniform shape wherein each particle comprises:

an encapsulant dispersed throughout a plasticized matrix material comprising starch which is not substantially dextrinized, said matrix material comprising at least one member selected from the group consisting of durum wheat, semolina, vital wheat gluten, soy protein, hydrocolloids, casein, and gelatin, and at least one plasticizer comprising water,

wherein said encapsulant comprises at least one pharmaceutical component, nutraceutical component, nutritional component, fragrance component, or biologically active component,

wherein the encapsulant and plasticized matrix material form an at least substantially homogeneous mixture,

wherein the amount of said encapsulant is from about 3% by weight to about 50% by weight, based upon the weight of the matrix material, and

wherein the amount of said matrix material is ~~at least~~ about 40% or more by weight, based upon the weight of the final encapsulated product.

84. (Original) An encapsulated product according to claim 83 wherein said matrix material comprises semolina or durum wheat.

85. (Original) An encapsulated product according to claim 83 wherein said encapsulant comprises at least one member selected from the group consisting of enzymes and microorganisms.

86-90. (Canceled)

91. (Previously presented) An encapsulated product according to claim 25, comprising about 3% by weight to about 50% by weight of the encapsulant, based upon the weight of the matrix material.

92. (Previously presented) An encapsulated product according to claim 25, comprising about 5% by weight to about 20% by weight of the encapsulant, based upon the weight of the matrix material.

93. (Previously presented) An encapsulated product according to claim 25, wherein the encapsulant is in liquid form.

94. (Withdrawn) An encapsulated product according to claim 25, wherein the encapsulant is in solid form.

95. (Previously presented) An encapsulated product according to claim 52, comprising about 3% by weight to about 50% by weight of the encapsulant, based upon the weight of the matrix material.

96. (Previously presented) An encapsulated product according to claim 52, comprising about 5% by weight to about 20% by weight of the encapsulant, based upon the weight of the matrix material.

97. (Previously presented) An encapsulated product according to claim 83, comprising about 5% by weight to about 20% by weight of the encapsulant, based upon the weight of the matrix material.

98-100. (Canceled)

101. (Previously presented) An encapsulated product according to Claim 25 wherein said plasticized mass comprises from about 60% by weight to about 95% by weight of at least one matrix material.

102. (Canceled)

103. (Previously presented) An encapsulated product according to Claim 52 comprising from about 60% by weight to about 95% by weight of the matrix material, based upon the weight of the final encapsulated product.

104. (Canceled)

105. (Previously presented) An encapsulated product according to Claim 83 comprising from about 60% by weight to about 95% by weight of the matrix material, based upon the weight of the final encapsulated product.

106-107. (Canceled)

108. (Previously presented) An encapsulated product according to claim 25 wherein said matrix material comprises at least one member selected from the group consisting of durum wheat, semolina, wheat flour, wheat gluten, native or modified starches, soy protein, casein, and gelatin.

109. (Previously presented) An encapsulated product according to claim 25 wherein said matrix material comprises at least one member selected from the group consisting of durum wheat, semolina, wheat flour, wheat gluten, native starches and modified starches.

110. (Previously Presented) An encapsulated product according to claim 27 wherein said matrix material comprises at least one member selected from the group consisting of durum wheat and semolina.